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with Bi-Flex™

RESPIRONICS®

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PEOPLE, PRODUCTS, PROGRAMS

D-92

Featuring® Encore SmartCard™

Featuring DIGITAL Auto-Trak Sensitivity

Service Manual

RESPIRONICS®

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RESPIRONICS®

Limited Warranty

Respironics warrants that the BiPAP Pro Bi-Level System shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two years from the date of sale by Respironics. If the product fails to perform in accordance with the product specifications, Respironics will repair or replace - at its option - the defective material or part. Respironics will pay customary freight charges from Respironics to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to materials or workmanship.

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Overview: BiPAP Pro Bi-Level System

Warranty		Details the Respironics warranty
Chapter 1:	**Introduction**	Lists the chapters included in this manual.
Chapter 2:	**Warnings, Cautions, and Notes**	Introduces the BiPAP Pro Bi-Level System.
Chapter 3:	**Specifications, Features, Descriptions, and Theory of Operation**	Describes the theory of operation for the BiPAP Pro Bi-Level System, including basic operations of the subsystems.
Chapter 4:	**System Setup Procedures**	Details system setup, including instructions on the Therapy Menu Display Screens and Required, Alternate, and Optional Patient Accessories.
Chapter 5:	**Routine Maintenance**	Provides cleaning and routine maintenance instructions.
Chapter 6:	**Troubleshooting and Diagnostics**	Provides troubleshooting flow charts and error code definitions.
Chapter 7:	**Repair and Replacement**	Describes detailed procedures of removing and installing all major components within the unit, including graphics and photographs for visual identification.
Chapter 8:	**Testing**	Includes the Performance Verification, Performance Verification Data Sheet, Calibration, and Final Testing.
Appendix A:	**Tools and Equipment**	Details the necessary tools and test equipment required for servicing.
Appendix B:	**Schematics**	Provides Printed Circuit Assembly (PCA) schematics.

NOTE: These are proprietary and are used for reference only.

Index:		Item location guide.

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Chapter 1: Introduction

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Chapter 1: Introduction

1.1 BiPAP Pro Bi-Level System Overview

The BiPAP Pro Bi-Level System (BiPAP Pro), shown in Figure 1-1, is a microprocessor-controlled device that delivers two fixed levels of therapy. The Inspiratory Positive Airway Pressure (IPAP) level is set for inspiratory breaths and the Expiratory Positive Airway Pressure (EPAP) level is set for expiratory breaths. A Comfort Control feature is available to set the transition time from EPAP to IPAP and a Bi-Flex mode can adjust bi-level therapy by inserting a small amount of pressure relief during the latter stages of inspiration and during active exhalation. A Ramp feature is also provided, which allows the user to lower the pressures for a preset time period. The lower pressure may help the user fall asleep at a low, comfortable pressure.

The unit incorporates a control pad with a Liquid Crystal Display (LCD), Light-Emitting Diode (LED), operational keys, internal audible and visual alarms, a Ramp feature, and a communications connector for use with the Encore® Data Management Software (Version 3.0 or higher). The unit may be operated using either AC (90 - 264 VAC) or DC (11.5 - 17 VDC) power.

Figure 1-1
BiPAP Pro Bi-Level System

1.2 Service Notice

This service manual was prepared by Respironics primarily for use by technicians to service the BiPAP Pro Bi-Level System. The individuals using this manual to service the BiPAP Pro Bi-Level System should have prior training or experience servicing ventilatory devices.

Only limited repairs and testing may be performed on the BiPAP Pro Bi-Level unit. For any major repairs, calibration of the BiPAP Pro Bi-Level System must be performed at a Respironics Service Center equipped with the proper calibration equipment.

1.3 Technical Support Statement

Respironics is committed to customer satisfaction and may be contacted with any questions or for technical support. For technical assistance or replacement part ordering information contact Respironics Customer Satisfaction.

U.S. and Canada

Phone: **1-800-345-6443**
Fax: **1-800-886-0245**

International

Phone: **1-724-387-4000**
Fax: **1-724-387-5012**

Visit Respironics Home Page on the World Wide Web at:

www.respironics.com

service@respironics.com

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Notes

Chapter 2: Warnings, Cautions, and Notes

WARNING:	Indicates the possibility of injury to the patient, operator, or technician.
CAUTION:	Indicates the possibility of damage to the device.
NOTE:	Places emphasis on an operating characteristic.

2.1 WARNINGS

2.1.1 Safety

- This device is intended for adult use only.
- This device is not intended for life support or life sustaining applications.
- The instructions in this manual are not intended to supersede established medical protocols.

2.1.2 Operational

- This warning applies to most Positive Airway Pressure devices. At low Expiratory Positive Airway Pressures (EPAP) pressure, the air flow through the exhalation port may not be enough to clear all of the exhaled gas (CO_2) from the mask. You may breathe in some of the air that you have exhaled.
- Do not use this device if the room temperature is warmer than 95°F (35°C). If this device is used at room tempera tures warmer that 95°F (35°C), the temperature of the airflow may exceed 106°F (41°C). this could cause iritation to your airway.
- If oxygen is used with this device, the oxygen flow must be turned off when the device is turned off. If the device's air flow is turned off and the oxygen flow is left on, oxygen may accumulate in the BiPAP Pro Bi-Level System enclosure and may create a risk of fire. This warning applies to most types of CPAP and Bi-Level devices.
- When supplemental oxygen is used at a fixed flow rate, inhaled oxygen concentrations will vary

  depending on pressure settings, patient breathing patterns, mask selection and leak rate.

Warnings (Continued)

- Oxygen supports combustion. Do not use oxygen in the presence of open flames, cigarette smoke, electrical spark, or other sources of ignition.
- Device is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- In situations where risk of contamination between the user and the device is high (e.g.: sleep lab devices; rental devices; users with respiratory infections), a low-resistance, main flow bacteria filter should be placed in-line between this device and the circuit.
- Most Bi-Level devices have the potential to induce rebreathing of exhaled air. To reduce this potential, use only Respironics circuit accessories, do not wear the mask and headgear for more than a few minutes while the unit is not operating, and do not block or try to seal the vent holes in the exhalation port.

2.1.3 Service

- Electronic components used in this device are subject to damage from static electricity. Repairs made to this device must be performed only in an antistatic, Electro-Static Discharge (ESD) protected environment.
- To assure the safety of the service technician and the specified performance of the device, Respironics recommends that only technicians having prior training or experience servicing ventilatory devices perform any repairs or adjustments to the BiPAP Pro Bi-Level System.
- High voltages are present inside this device. To avoid electrical shock, disconnect the electrical supply before attempting any repairs on the device.

2.1.4 Cleaning

- To avoid electrical shock, disconnect the electrical supply before cleaning the BiPAP Pro Bi-Level System. DO NOT immerse this device into any fluids.

2.2 CAUTIONS

- **Federal law (U.S.) restricts this device to sale by, or on the order of, a physician.**
- Care should be taken to avoid exposure of the BiPAP Pro Bi-Level System to temperatures at or near the extremes of those specified in Chapter 3. If exposure to such temperatures has occurred, the device should be allowed to return to room temperature before being turned on.
- Always use an intake filter when the BiPAP Pro Bi-Level System is in use.
- Never place liquids on or near the BiPAP Pro Bi-Level System.
- Discontinue using this device if any of the parts are damaged. Replace any damaged parts before continuing use.
- The information in this manual is provided for service personnel reference and is not intended for system setup or use. System setup should be performed by appropriate personnel using Home Care Provider Set-up Instructions.

2.3 NOTES

- Refer to the BiPAP Pro Bi-Level System User's Manual for product use additional warnings, cautions, and notes.

Additional WARNINGS, CAUTIONS, and NOTES are located throughout this manual.

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Chapter 3: Specifications, Features, Descriptions, and Theory of Operation

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Chapter 3: Specifications, Features, Descriptions, and Theory of Operation

3.1 Overview

This chapter describes the BiPAP Pro Bi-Level System specifications and system features, and provides a functional description and theory of operation of the unit.

3.2 Specifications

ENVIRONMENTAL:

Operating Temperature	41 - 95°F (5 - 35°C)
Storage Temperature	-4 - 140°F (-20 - 60°C)
Humidity	15 - 95% non-condensing
Outlet Air Temperature	Shall not exceed 106°F (41°C) when operating at a maximum ambient temperature of 95°F (35°C).

NOTE: The unit should be checked if the outlet temperature rise is as much as 18°F (10°C) higher than room temperature measured at the end of Respironics 6 ft. flexible tubing.

Atmospheric Pressure	83 - 102 kPascals (storage: 50 - 102 kPascals)
Elevation	0 - 5,500 ft. (0 - 167 km) with automatic altitude adjustment.
Noise Level	No specification is given because various instruments, test procedures and unit operating conditions produce varying results.

FUSES:

Fuses	There are no replaceable fuses.

PHYSICAL:

Electrical Safety	IEC 601-1, general safety requirement for medical devices
Dimensions	12.50″ (L) x 7.250″ (W) x 5.75″ (H) (31.75 x 18.4 x 14.6 cm)
Weight	5.8 lbs. (2.6 kg)

ELECTRICAL:

AC Input Voltage	90 - 264 VAC 47 - 63 Hz
DC Voltage	11.5 - 17.0 VDC
AC Current Consumption	1.0 A maximum
DC Current Consumption	4.0 A maximum
Power Consumption	90 VA maximum
Class	Class II 2-prong AC power inlet
Type	Type BF

Specifications (Continued)

FUNCTIONS:

Modes:	CPAP Bi-Level Bi-Flex

EMC NORMATIVE DOCUMENTS:

This product complies with the requirements found in the following documents.

IEC 601-1-2	Medical electrical equipment, general requirements for safety, and electromagnetic compatibility.
IEC 1000-2	Electrostatic discharge requirements for industrial process measurement and control equipment.
IEC 1000-3	Radiated electromagnetic field requirements for industrial process measurement and control equipment.
IEC 1000-4	Electrically fast transients for industrial process measurement and control equipment.
CISPR 11	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific, and medical (ISM) equipment.

RAMP:

NOTE: The Bi-Level ramp cycle will not operate if the EPAP pressure setting is 3.0 cm H_2O.

Minimum Ramp Pressure	EPAP pressure must be 1.0 cm H_2O higher than the minimum ramp pressure
Ramp Resolution	.25 cm H_2O or less
Ramp Time	5 - 45 minutes
Ramp Time Resolution	5 minute increments

ALTITUDE COMPENSATION:

Pressure Range	83 - 102 kPascals
	Automatic Altitude Adjustment

COMPLIANCE METER:

Compliance Meter (LCD)	Total Operation Time Therapy Time Percent Memory Remaining

Specifications (Continued)

PRESSURE:

AC Operation	3.0 - 20.0 cm H_2O
DC Operation	3.0 - 20.0 cm H_2O
CPAP Mode	3.0 - 20.0 cm H_2O
Bi-Level Mode	IPAP Pressure Range 3.0 - 20.0 cm H_2O EPAP Pressure Range 3.0 - 20.0 cm H_2O
Resolution	1.0 cm H_2O

NOTE: Pressure accuracy measurements shall be taken at the end of a six foot patient circuit with a Whisper Swivel II exhalation port.

Static Pressure Accuracy	1.25 cm H_2O of the displayed pressure setting
Dynamic Pressure Accuracy	Within 1.5 cm H_2O of the pressure values established during verification of the Static Pressure accuracy

THERAPY MEMORY:

Therapy Memory	Retrievable by Encore Software (version 3.0 or later)

STORAGE:

Data Storage	Data storage shall be on a removable contact SmartCard

CPAP Mode

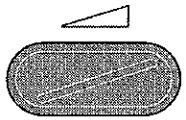
Max Capacity	6 months of data comprised of 3 sessions per 24-hour period, with 2.5 ramps per session
Content	Separate memory areas for prescription information and data storage

Bi-Level Mode

Max Capacity	6 months of data comprised of 3 sessions per 24-hour period, with 2.5 ramps per session
Content	Separate memory areas for prescription information and data storage

3.3 System Features

AC Power Connector	Connect AC power here.
Air Outlet Port	Connect flexible tubing here.
Communications Connector	Null Modem Communications Cable For clinical use with Encore Data Management Software (version 3.0 or higher).
DC Power Connector	Optional DC power connection.
LCD Display	Displays all system settings, total operating time, and therapy hours.
Filter Cap & Filters	The pollen filter screens out normal household dust and pollens. This must be in place at all times when operating the BiPAP Pro Bi-Level System. An ultra-fine filter is also included for more complete filtration of very fine particles. The filter cap can be positioned to direct the air flow away from the bedside.
Pressure On / Off Button	This button turns the air flow on or off.
Ramp / Reset Button	This button decreases the pressure to the minimum ramp pressure setting.
LED Signal Light	The green light signals when the BiPAP Pro Bi-Level System is ready for use. The light willgo out when the air flow is turned on. A flashing light signals that the unit needs to be serviced.
User Buttons	These buttons can be used to change some of the System settings.
AC Power Cord	IEC 320 style.

Symbol	Meaning
	Attention, consult accompanying documents
	Type BF Applied Part
	Class II for Protection Against Electric Shock
	Pressure On / Off
	**Ramp Start**
CE 0123	**European CE Marking**
IPXO	**Ordinary Equipment**

3.4 Functional Description

The BiPAP Pro Bi-Level System is a microprocessor controlled Bi-Level Positive Airway Pressure (BiPAP) device that produces Bi-Level pressure.

The BiPAP Pro Bi-Level System operates in two modes. The Continuous Positive Airway Pressure (CPAP) mode delivers continuous positive airway pressure, maintaining a constant level of pressure throughout the breathing cycle. The Bi-Level mode delivers two (e.g., inspiratory and expiratory) levels of positive pressure. During exhalation the pressure is variably positive or near ambient. The inspiratory level is variably positive and always higher than or equal to the expiratory level. The Bi-Level System monitors the flow pressure to determine when the patient is inhaling or exhaling. The unit switches between inspiratory and expiratory states and delivers the desired IPAP and EPAP pressure accordingly.

The BiPAP Pro Bi-Level System offers a Comfort Control feature which allows the setting of transition time from EPAP to IPAP. This parameter is adjustable so the patient can find the most comfortable setting. In Bi-Level mode, the Bi-Flex level feature can adjust bi-level therapy by inserting a small amount of pressure relief during the latter stages of inspiration and during active exhalation.

Integral to the generation of air flow is the blower assembly. Ambient air is drawn through the air intake filters, and pressurized by the energized blower. Ultimately, therapeutic pressure is provided to the patient via the patient circuit. The microprocessor regulates the motor speed, which in turn adjusts and controls the pressure.

The BiPAP Pro Bi-Level System control pad, which includes four push buttons and a Light-Emitting Diode (LED) signal light, are the primary means by which the patient therapy is controlled. Patients have limited access to unit parameters.

The units may be powered from either AC (90 - 264 VAC) or from DC (11 - 17 VDC). AC power enters the units via an AC inlet and appropriate power cord. A DC power cord connector enables the patient to use the system when AC voltage is not accessible.

The two system filters, the pollen and the ultra-fine, ensure optimum operation for the user. An air outlet port allows for connection to the patient circuit.

The patient circuit is made up of flexible tubing, outlet swivel with pressure tubing, exhalation port, and nasal mask. The unit applies Bi-Level pressures to the patient's upper airway to keep the airway open during sleep. Air flow generated from the unit is directed to the patient via a mask and flexible tubing that connects to the air outlet port of the unit.

The ramp feature, available in both modes, lets the user reduce the pressure from the BiPAP Pro Bi-Level System so the patient can fall a sleep at a lower, more comfortable pressure at any time or as many times as needed during the night.

The BiPAP Pro Bi-Level System is intended to deliver BiPAP and CPAP therapy only. It is not intended for life support or life sustaining applications. The following sections describe the major components of the BiPAP Pro Bi-Level System and its basic theory of operation.

3.5 Theory of Operation

3.5.1 Control Pad & Liquid Crystal Display (LCD)

The control pad consists of a signal light and four user buttons (ramp button, On / Off button, and right and left user buttons for other functions). The On / Off button activates and deactivates the pressure. The range of pressure is 3.0 to 20.0 cm H_2O with AC and DC operation. The Ramp Button initiates a ramp cycle which incrementally and automatically increases the pressure. The Ramp begins at the minimum ramp pressure setting, and over the specified time period, increases until the therapeutic pressure is reached. Ramp Time is adjustable from 5 to 45 minutes in five minute increments. The signal light indicates power and pressure On / Off status. An LCD is used to show various operating parameters while the unit is powered.

3.5.2 Main Printed Circuit Assembly (Main PCA)

Control of the BiPAP Pro Bi-Level System is accomplished with the use of a 16-bit microcontroller. The device provides digital I/O, timers, a QSPI interface, serial communication lines, an 8-channel A/D converter, and a 16-bit data bus with built-in chip selects.

The motor used in the BiPAP Pro Bi-Level System is a three phase Wye connected design with the internal motor common. The three phases are driven in a push pull fashion by three P-channel and three N-channel MOSFETS. The output is then processed by the A/D converter.

Motor commutation of the three windings is accomplished with the use of a sensorless motor controller chip. This provides the correct commutation pattern to the three phases of the motor. An align and start-up sequence is initiated when the brake and align inputs are allowed to float. Once the motor is rotating, the back-EMF of the motor is sensed. This governs the commutation of each phase.

The speed of the motor is controlled through a DAC driving the VSPEED of the sensorless motor controller chip. The motor controller chip provides a TACH signal to the A/D converter in order to indicate motor speed. The TACH feedback is then read with an Input Capture of the A/D converter and is compared to the desired speed vs. pressure table.

Theory of Operation (Continued)

3.5.3 Encore SmartCard

The BiPAP Pro Bi-Level System is delivered with the Encore SmartCard installed. The SmartCard is a plastic card similar in size and shape to your normal credit card. But instead of holding information on a magnetic strip, it holds it in a small silicon chip embedded into the card.

When installed into the BiPAP Pro Bi-Level System, the SmartCard records the date, time at pressure, pressure levels, and duration of each use. Using the Encore Software (version 3.0), the usage data can be downloaded and viewed.

The SmartCard can also be programmed with the patient's prescription by using the Encore Software and SmartCard reader/writer. When the programmed SmartCard is inserted into the device, the prescription settings are automatically transferred into the device and erased from the SmartCard. The SmartCard will then start to collect patient data.

3.5.4 Flow Sensor Circuitry

The flow sensor circuitry works on a mass flow sensor. The sensor has a range of 0 to 200 lpm based on the flow element used in the BiPAP Pro Bi-Level System. The instrumentation amplifier with filter produces an output that is equal to 1 lpm and a second output that is equal to 200 lpm. The signal is read differently as FLOW1 and FLOW2. Potentiometers are used to eliminate any component offsets and to adjust the circuit gain.

3.5.5 Pressure Sensor Circuitry

The pressure sensor circuitry is based upon a SenSym pressure sensor. This sensor has an operating range of 0 to 1 PSI (70.0 cm H_2O). The op amp circuits, including the instrumentation amplifier and gain offset potentiometer, are used to produce a signal that is read by the A/D converter and a signal that is used as the pressure reference to the valve controller.

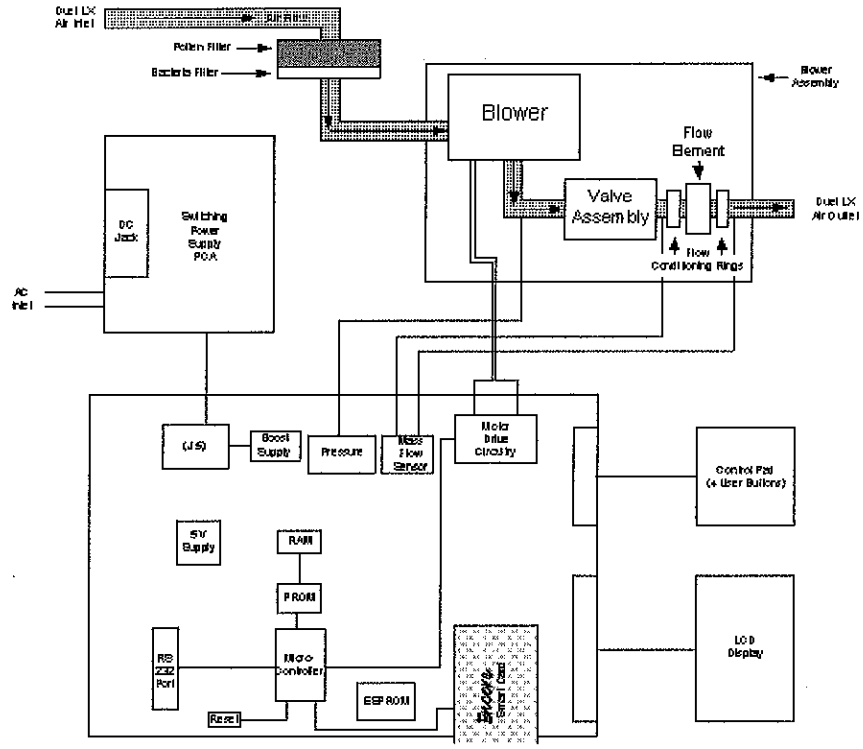
3.5.6 Power Supply Printed Circuit Assembly (Power Supply PCA)

The BiPAP Pro Bi-Level System has a switching power supply which is built on an independent PCA and mounted immediately on top of the unit's enclosure insert. The switching power supply operates properly on any AC voltage between 90 - 264 VAC; 47 - 63 HZ input range with EMI filter through an on-board DC jack. The power supply has an output voltage of 29 V (+/-3 V) at 1.7A under AC operation and an output voltage of 24.5 V (+/- 1.5V) at 1.9 A under DC operation.

3.5.7 Valve Control

The BiPAP Pro Bi-Level System utilizes a sleeve valve to control inspiratory and expiratory pressure. This is accomplished through the use of an analog PID controller. A DAC is used to set the reference pressure. Once this is set, the analog control loop compares the reference pressure to the actual pressure from the pressure circuitry. The analog control loop then automatically adjusts the valve position to regulate the reference pressure.

3.6 Block Diagram



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Chapter 4: System Setup Procedures

4.1 Overview

This section provides an overview of the system setup including detailed instructions on the therapy menu display screens. Refer to Chapter 7, Repair and Replacement, or Chapter 5, Routine Maintenance, for filter and filter cap installation instructions.

NOTE:	The BiPAP Pro Bi-Level System is delivered with an Encore SmartCard installed.
NOTE:	This section provides directions for accessing the Therapy menu. Prescribed therapy can be set by using the SmartCard or by the Therapy menu. (The patient's User's Manual provides directions to access only the Patient menu, which limits access to settings. To prevent patients from tampering with the settings, the directions to access the Therapy menu should not be revealed to the patient.)
CAUTION:	If the SmartCard is not installed, the device usage will not be recorded.
CAUTION:	If the system is not turned off properly, data will not be recorded to the SmartCard.

4.2 Programming a SmartCard

Step 1 Connect a Respironics SmartCard reader/writer directly to a PC computer following the instructions included with the reader/writer. Remove the SmartCard from the BiPAP Bi-Level System and insert it into the reader/writer.

Step 2 Open the patient's file in the Encore Software (or create a new patient file). Choose "SmartCard Wizard" from the "Communications" menu. Following the prompts, complete the patients prescription. The patient's name and prescription will be saved on the SmartCard.

Step 3 Remove the SmartCard from the Reader/Writer. If desired, write the patient's name on the front of the card.

4.3 Changing Settings using a SmartCard for Bi-Level Mode.

Step 1 Inserting the SmartCard

Make sure that the BiPAP Pro Bi-Level System is plugged into an electrical outlet. Insert the programmed SmartCard into the slot on the left side of the unit (logo side facing up). When the "blower off" screen appears, there will be an arrow in the upper right corner indicating that the card is inserted correctly.

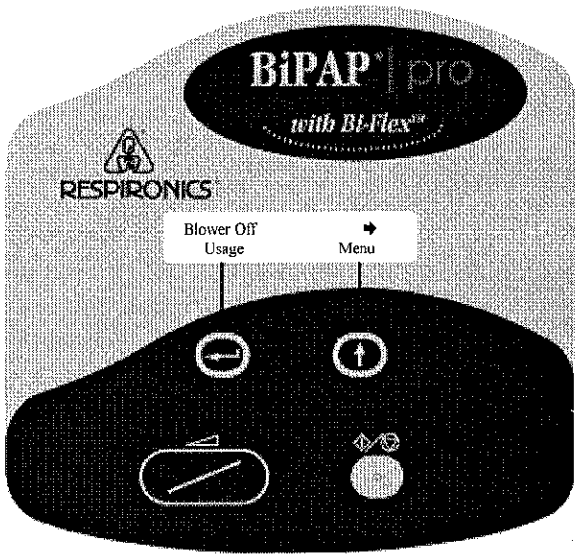

Figure 4-1
Card Inserted Correctly Screen

Figure 4-2
Card Inserted